

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Currently Amended): A preliposome-lyophilate comprising an amphipathic lipid, a bioactive agent and a non-lipid surfactant, wherein the lyophilate (a) was made by a method comprising lyophilizing a composition comprising said amphipathic lipid, said bioactive agent, t-butanol, water, and said surfactant, but lacking liposomes; and (b) upon reconstitution with aqueous solution, results in a distribution of liposomes having a median diameter of less than 1  $\mu\text{m}$   ~~$\mu\text{M}$~~ .
2. (Cancelled)
3. (Cancelled)
4. (Previously Presented): The preliposome-lyophilate of claim 1 wherein said surfactant is nonionic.
5. (Previously Presented): The preliposome-lyophilate of claim 4 wherein said surfactant is a polyoxyethylene sorbitan carboxylate surfactant.
6. (Previously Presented): The preliposome-lyophilate of claim 5 wherein said surfactant is polyoxyethylene sorbitan monolaurate.
7. (Previously Presented): The preliposome-lyophilate of claim 6 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the preliposome-lyophilate.

8. (Previously Presented): The preliposome-lyophilate of claim 1 wherein said surfactant comprises from about 5 mole % to about 0.1 mole % of the lipid content of the preliposome-lyophilate.

9. (Previously Presented): The preliposome-lyophilate of claim 8 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the preliposome-lyophilate.

Claims 10-51 (Cancelled)

52. (Previously Presented): The preliposome-lyophilate of claim 1, said preliposome lyophilate being halogenated solvent-free.

53. (Currently Amended): A preliposome-lyophilate comprising an amphipathic ~~amphipathic~~ lipid, a bioactive agent and a non-lipid surfactant, wherein said lyophilate (a) was made by a method comprising lyophilizing a composition comprising said amphipathic lipid, said bioactive agent, t-butanol, water, and said surfactant, but lacking liposomes, and (b) upon reconstitution in aqueous solution results in a distribution of ~~has the ability to form~~ liposomes having a median diameter of less than 400 nm ~~when reconstituted in aqueous solution~~.

54. (Previously Presented): The preliposome-lyophilate of claim 53 wherein said surfactant is nonionic.

55. (Previously Presented): The preliposome-lyophilate of claim 54 wherein said nonionic surfactant is selected from the group consisting of polyoxyethylene sorbitan monolaurate having a molecular weight of approximately 1300 and polyoxyethylene sorbitan monooleate having a molecular weight of approximately 1350.

56. (Cancelled)

57. (Currently Amended): A preliposome-lyophilate, wherein said lyophilate,

upon reconstitution with aqueous solution, results in a distribution of liposomes having a median diameter of less than 400 nm; said lyophilate being produced by a process comprising:

- (a) preparing a composition comprising at least one amphipathic lipid, a non-lipid surfactant, and a bioactive agent dissolved in an aqueous/t-butanol solvent system ~~and a non-lipid surfactant~~; and
- (b) lyophilizing said composition to form said preliposome-lyophilate, wherein said composition does not comprise liposomes at the time of said lyophilizing.

58. (Cancelled)

59. (Previously Presented): The preliposome-lyophilate of claim 57 wherein said surfactant is nonionic.

60. (Previously Presented): The preliposome-lyophilate of claim 59 wherein said surfactant is a polyoxyethylene sorbitan carboxylate surfactant.

61. (Previously Presented): The preliposome-lyophilate of claim 60 wherein said surfactant is polyoxyethylene sorbitan monolaurate.

62. (Previously Presented): The preliposome-lyophilate of claim 60 wherein said surfactant is polyoxyethylene sorbitan monooleate.

63. (Previously Presented): The preliposome-lyophilate of claim 61 or claim 62 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the lyophilate.

64. (Previously Presented): The preliposome-lyophilate of claim 57 wherein said surfactant comprises from about 5 mole % to about 0.1 mole % of the lipid content of the lyophilate.

65. (Previously Presented): The preliposome-lyophilate of claim 64 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the lyophilate.
66. (Currently Amended): A lyophilate comprising at least one amphipathic lipid, a bioactive agent and a non-lipid surfactant, said surfactant being present in an amount less than 4 mole % of the lipid content of said lyophilate, wherein said lyophilate was made by a method comprising lyophilizing a composition comprising said at least one amphipathic lipid, said bioactive agent, t-butanol, water, and said surfactant, but lacking liposomes, and wherein said lyophilate results in ~~is capable of forming~~ a distribution of liposomes in about one minute with hand-shaking upon addition of aqueous solution, said distribution of liposomes having a median diameter of less than 400 nm.
67. (Cancelled)
68. (Previously Presented): The lyophilate of claim 66 wherein said surfactant is nonionic.
69. (Previously Presented): The lyophilate of claim 68 wherein said surfactant is a polyoxyethylene sorbitan carboxylate surfactant.
70. (Previously Presented): The lyophilate of claim 69 wherein said surfactant is polyoxyethylene sorbitan monolaurate.
71. (Previously Presented): The lyophilate of claim 69 wherein said surfactant is polyoxyethylene sorbitan monooleate.
72. (Currently Amended): The lyophilate of claim ~~66~~ 67 wherein the bioactive agent is selected from the group consisting of an antifungal agent, an antineoplastic agent, an antibiotic, an adjuvant, a vaccine, a contrast agent, a diagnostic agent, a drug targeting agent and a genetic fragment.

73. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is an antifungal agent.

74. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is an antineoplastic agent.

75. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is an antibiotic.

76. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is an adjuvant.

77. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is a vaccine.

78. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is a contrast agent.

79. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is a diagnostic agent.

80. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is a drug targeting agent.

81. (Previously Presented): The lyophilate of claim 72 wherein the bioactive agent is a genetic fragment.

82. (Previously Presented): The preliposome-lyophilate of claim 5 wherein said surfactant is polyoxyethylene sorbitan monooleate.

83. (Previously Presented): The preliposome-lyophilate of claim 1 wherein said surfactant is present in an amount less than 4 mole % of the lipid content of said lyophilate.

84. (Previously Presented): The preliposome-lyophilate of claim 1 wherein said reconstitution is achieved by hand-shaking for about one minute upon addition of said aqueous solution.
85. (Previously Presented): The preliposome-lyophilate of claim 1, 4, 53, 54, 55, 57, or 59 wherein the amphipathic lipid is a phospholipid.
86. (Currently Amended): The lyophilate of claim 66, ~~67~~, 68, 72, 74, or 84 wherein the amphipathic lipid is a phospholipid.
87. (New): A preliposome-lyophilate comprising an amphipathic lipid and a non-lipid surfactant, wherein the lyophilate (a) was made by a method comprising lyophilizing a composition comprising said amphipathic lipid, t-butanol, water, and said surfactant, but lacking liposomes and halogenated solvent; and (b) upon reconstitution with aqueous solution, results in a distribution of liposomes having a median diameter of less than 1  $\mu\text{m}$ , which liposomes are suitable for administration to an animal.
88. (New): The preliposome-lyophilate of claim 87 wherein said surfactant is nonionic.
89. (New): The preliposome-lyophilate of claim 88 wherein said surfactant is a polyoxyethylene sorbitan carboxylate surfactant.
90. (New): The preliposome-lyophilate of claim 89 wherein said surfactant is polyoxyethylene sorbitan monolaurate.
91. (New): The preliposome-lyophilate of claim 90 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the preliposome-lyophilate.
92. (New): The preliposome-lyophilate of claim 87 wherein said surfactant comprises from about 5 mole % to about 0.1 mole % of the lipid content of the preliposome-lyophilate.

93. (New): The preliposome-lyophilate of claim 92 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the preliposome-lyophilate.
94. (New): A preliposome-lyophilate comprising an amphipathic lipid and a non-lipid surfactant, wherein said lyophilate (a) was made by a method comprising lyophilizing a composition comprising said amphipathic lipid, t-butanol, water, and said surfactant, but lacking liposomes and halogenated solvent, and (b) upon reconstitution in aqueous solution results in a distribution of liposomes having a median diameter of less than 400 nm, which liposomes are suitable for administration to an animal.
95. (New): The preliposome-lyophilate of claim 94 wherein said surfactant is nonionic.
96. (New): The preliposome-lyophilate of claim 95 wherein said nonionic surfactant is selected from the group consisting of polyoxyethylene sorbitan monolaurate having a molecular weight of approximately 1300 and polyoxyethylene sorbitan monooleate having a molecular weight of approximately 1350.
97. (New): A preliposome-lyophilate, wherein said lyophilate, upon reconstitution with aqueous solution, results in a distribution of liposomes having a median diameter of less than 400 nm, which liposomes are suitable for administration to an animal; said lyophilate being produced by a process comprising:
- (a) preparing a composition comprising at least one amphipathic lipid and a non-lipid surfactant dissolved in an aqueous/t-butanol solvent system that lacks halogenated solvents; and
  - (b) lyophilizing said composition to form said preliposome-lyophilate, wherein said composition does not comprise liposomes at the time of said lyophilizing.
98. (New): The preliposome-lyophilate of claim 97 wherein said surfactant is nonionic.
99. (New): The preliposome-lyophilate of claim 98 wherein said surfactant is a polyoxyethylene sorbitan carboxylate surfactant.

100. (New): The preliposome-lyophilate of claim 99 wherein said surfactant is polyoxyethylene sorbitan monolaurate.
101. (New): The preliposome-lyophilate of claim 99 wherein said surfactant is polyoxyethylene sorbitan monooleate.
102. (New): The preliposome-lyophilate of claim 100 or claim 101 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the lyophilate.
103. (New): The preliposome-lyophilate of claim 97 wherein said surfactant comprises from about 5 mole % to about 0.1 mole % of the lipid content of the lyophilate.
104. (New): The preliposome-lyophilate of claim 103 wherein said surfactant comprises from about 4 mole % to about 2 mole % of the lipid content of the lyophilate.
105. (New): A lyophilate comprising at least one amphipathic lipid and a non-lipid surfactant, said surfactant being present in an amount less than 4 mole % of the lipid content of said lyophilate, wherein said lyophilate was made by a method comprising lyophilizing a composition comprising said at least one amphipathic lipid, t-butanol, water, and said surfactant, but lacking liposomes and halogenated solvent, and wherein said lyophilate results in a distribution of liposomes in about one minute with hand-shaking upon addition of aqueous solution, said distribution of liposomes having a median diameter of less than 400 nm and which are suitable for administration to an animal.
106. (New): The lyophilate of claim 105 further comprising a bioactive agent.
107. (New): The lyophilate of claim 105 wherein said surfactant is nonionic.
108. (New): The lyophilate of claim 107 wherein said surfactant is a polyoxyethylene sorbitan carboxylate surfactant.



109. (New): The lyophilate of claim 108 wherein said surfactant is polyoxyethylene sorbitan monolaurate.

110. (New): The lyophilate of claim 108 wherein said surfactant is polyoxyethylene sorbitan monooleate.

111. (New): The lyophilate of claim 106 wherein the bioactive agent is selected from the group consisting of an antifungal agent, an antineoplastic agent, an antibiotic, an adjuvant, a vaccine, a contrast agent, a diagnostic agent, a drug targeting agent and a genetic fragment.

112. (New): The lyophilate of claim 111 wherein the bioactive agent is an antifungal agent.

113. (New): The lyophilate of claim 111 wherein the bioactive agent is an antineoplastic agent.

114. (New): The lyophilate of claim 111 wherein the bioactive agent is an antibiotic.

115. (New): The lyophilate of claim 111 wherein the bioactive agent is an adjuvant.

116. (New): The lyophilate of claim 111 wherein the bioactive agent is a vaccine.

117. (New): The lyophilate of claim 111 wherein the bioactive agent is a contrast agent.

118. (New): The lyophilate of claim 111 wherein the bioactive agent is a diagnostic agent.

119. (New): The lyophilate of claim 111 wherein the bioactive agent is a drug targeting agent.

120. (New): The lyophilate of claim 111 wherein the bioactive agent is a genetic fragment.

121. (New): The preliposome-lyophilate of claim 89 wherein said surfactant is polyoxyethylene sorbitan monooleate.
122. (New): The preliposome-lyophilate of claim 87 wherein said surfactant is present in an amount less than 4 mole % of the lipid content of said lyophilate.
123. (New): The preliposome-lyophilate of claim 87 wherein said reconstitution is achieved by hand-shaking for about one minute upon addition of said aqueous solution.
124. (New): The preliposome-lyophilate of claim 87, 88, 94, 95, 96, 97, or 98 wherein the amphipathic lipid is a phospholipid.
125. (New): The lyophilate of claim 105, 106, 107, 111, 113, or 123 wherein the amphipathic lipid is a phospholipid.